105TH CONGRESS
1ST SESSION

S. 830

AMENDMENTS

In the House of Representatives, U. S.,

October 7, 1997.

Resolved, That the bill from the Senate (S. 830) entitled ''An Act to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.'', do pass with the following

AMENDMENTS:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food and Drug Administration Regulatory Modernization Act of 1997''.

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—IMPROVING REGULATION OF DRUGS

SEC. 101. FEES RELATING TO DRUGS.

(a) FINDINGS.—Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in

substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of , and , from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth at Cong. Rec. (daily ed. , 1997).

(b) DEFINITIONS.—Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking "Service Act, and" and inserting "Service Act,"; and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.";

(2) in the second sentence of paragraph (3)—

(A) by striking "Service Act, and" and inserting "Service Act,"; and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.";

(3) in paragraph (4), by striking "without" and inserting "without substantial";

(4) by amending the first sentence of paragraph (5) to read as follows:

"(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other and at which one or more prescription drug products are manufactured in final dosage form.".

(5) in paragraph (7)(A)—

(A) by striking "employees under contract" and all that follows through "Administration," the second time it occurs and inserting "contractors of the Food and Drug Administration,"; and

(B) by striking "and committees," and inserting "and committees and to contracts with such contractors,";

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking "August of" and inserting "April of"; and

(ii) by striking "August 1992" and inserting "April 1997";

(B) in subparagraph (B), by striking "1992" and inserting "1997"; and

(C) by striking the second sentence; and

(7) by adding at the end the following:

"(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has power to control, both of the business entities.".

(c) AUTHORITY TO ASSESS AND USE DRUG FEES.—

(1) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(A) by striking "Beginning in fiscal year 1993" and inserting "Beginning in fiscal year 1998";

(B) in paragraph (1)—

(i) by striking subparagraph (B) and inserting the following:

"(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.";

(ii) in subparagraph (D)—

(I) in the subparagraph heading, by striking "NOT ACCEPTED" and inserting "REFUSED";

(II) by striking "50 percent" and inserting "75 percent";

(III) by striking "subparagraph (B)(i)" and inserting "subparagraph (B)"; and

(IV) by striking "not accepted" and inserting "refused"; and

(iii) by adding at the end the following:

"(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a

rare disease or condition with regard to the indication proposed in such supplement.

"(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application for an indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

"(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.";

(C) by striking paragraph (2) and inserting in lieu the following:

"(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each person that is named as the applicant in a human drug application, and after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than 1 applicant, the establishment fee for the

fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

"(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

"(i) that did not manufacture the product in the previous fiscal year; and

"(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.".

(D) in paragraph (3)—

(i) in subparagraph (A)—

(I) in clause (i), by striking "is listed" and inserting "has been submitted for listing"; and

(II) by striking "Such fee shall be paid" and all that follows through "section 510." and inserting the following: "Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(ii) in subparagraph (B), by striking "505(j)." and inserting the following: "505(j), under an abbreviated application filed under section 507, or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.".

(2) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

"(1) APPLICATION AND SUPPLEMENT FEES.—

"(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

"(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

"(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

"(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.".

(3) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) in the subsection heading, by striking "INCREASES AND";

(B) in paragraph (1)—

(i) by striking "(1) REVENUE" and all that follows through "increased by the Secretary" and inserting the following: "(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary";

(ii) in subparagraph (A), by striking "increase" and inserting "change";

(iii) in subparagraph (B), by striking "increase" and inserting "change"; and

(iv) by adding at the end the following flush sentence:

"The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.";

(C) in paragraph (2), by striking "October 1, 1992," and all that follows through "such schedule." and inserting the following: "September 30, 1997, adjust the establishment and prod-

uct fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).''; and

(D) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(4) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(A) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(B) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—'';

(C) in subparagraph (C) (as so redesignated by subparagraph (A)), by striking '', or'' and inserting a comma;

(D) in subparagraph (D) (as so redesignated by subparagraph (A)), by striking the period and inserting ", or";

(E) by inserting after subparagraph (D) (as so redesignated by subparagraph (A)) the following:

"(E) the applicant is a small business submitting its first human drug application to the Secretary for review."; and

(F) by striking "In making the finding in paragraph (3)," and all that follows through "standard costs." and inserting the following:

"(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

"(3) RULES RELATING TO SMALL BUSINESSES.—

"(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

"(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small

business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

"(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

"(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.".

(5) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(A) by striking "fiscal year 1993" and inserting "fiscal year 1997"; and

(B) by striking "fiscal year 1992" and inserting "fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)".

(6) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(A) in paragraph (1), by adding at the end the following: "Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropria-

tion account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "Acts" and inserting "Acts, or otherwise made available for obligation,"; and

(ii) in subparagraph (B), by striking "over such costs for fiscal year 1992" and inserting "over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997"; and

(C) by striking paragraph (3) and inserting the following:

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

"(A) $106,800,000 for fiscal year 1998;

"(B) $109,200,000 for fiscal year 1999;

"(C) $109,200,000 for fiscal year 2000;

"(D) $114,000,000 for fiscal year 2001; and

"(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

"(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.".

(7) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(A) by redesignating subsection (i) as subsection (j); and

(B) by inserting after subsection (h) the following:

"(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such

waiver, reduction, or refund not later than 180 days after such fee is due.".

(8) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees assessed prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

(d) ANNUAL REPORTS.—

(1) PERFORMANCE REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in subsection (a)(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(2) FISCAL REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each

fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect October 1, 1997.

(f) TERMINATION OF EFFECTIVENESS.—The amendments made by subsections (b) and (c) cease to be effective October 1, 2002, and subsection (d) ceases to be effective 120 days after such date.

SEC. 102. PEDIATRIC STUDIES OF DRUGS.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

"PEDIATRIC STUDIES OF DRUGS

"SEC. 505A. (a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric

studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D)(iii) and (iv) and (j)(4)(D)(iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research shall develop, prioritize, and publish an initial list of approved drugs for which ad-

ditional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

"(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsection (c)(3)(D)(ii) or (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D)(iii) and (iv) and (j)(4)(D)(iii) and

(iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall

be extended by a period of six months after the date the patent expires (including any patent extensions).

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

"(A) the sponsor of an application for an investigational new drug under section 505(i);

"(B) the sponsor of an application for a drug under section 505(b)(1); or

"(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

"(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written

request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

"(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

"(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a drug may occur after submission of reports of pediatric studies under

this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j), respectively, until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

"(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under section 505(b)(2) or (j) for a drug will be subject to the provisions of this section.

"(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups in which a drug is anticipated to be used.

"(h) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if

otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

"(i) RELATIONSHIP TO REGULATIONS.—Notwithstanding any other provision of law, if any pediatric study is required pursuant to regulations promulgated by the Secretary, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

"(j) SUNSET.—No period of market exclusivity shall be granted under this section based on studies commenced after January 1, 2002. The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program. The study and report shall examine all relevant issues, including—

"(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

"(2) the adequacy of the incentive provided under this section;

"(3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on lower income patients; and

"(4) any suggestions for modification that the Secretary deems appropriate.".

SEC. 103. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter VII is amended by adding at the end the following:

"SUBCHAPTER D—FAST TRACK PRODUCTS

"SEC. 741. FAST TRACK PRODUCTS.

"(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary shall facilitate the development and expedite the review of new drugs that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this section, such products shall be known as 'fast track products'.

"(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

"(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track product under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

"(2) LIMITATION.—Approval of a fast track product under this subsection may be subject to the requirements—

"(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate

endpoint or otherwise confirm the effect on the clinical endpoint; and

"(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period thereafter as the Secretary deems appropriate, at least 30 days prior to dissemination of the materials.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing), if—

"(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

"(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

"(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant (A) provides a schedule for submission of information necessary to make the application complete, and (B) pays any fee that may be required under section 736.

"(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) AWARENESS EFFORTS.—The Secretary shall—

"(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions applicable to fast track products established under this section; and

"(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.".

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary shall issue guidance for fast track products (as defined in section 741(a)(1) of the Federal Food, Drug, and Cosmetic Act) that describes the policies and procedures that pertain to section 741 of such Act.

SEC. 104. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SUBCHAPTER D—UNAPPROVED THERAPIES AND DIAGNOSTICS

"SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

"(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs (as defined in regulations prescribed by the Secretary) for the diagnosis or treatment of a serious disease or condition in emergency situations.

"(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to such physician after compliance with the provisions of this subsection, an investigational drug (as defined in regulations prescribed by the Secretary) for the diagnosis or treatment of a serious disease or condition if—

"(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose or treat the disease or condition involved, and that the risk to the person from the investigational drug is not greater than the risk from the disease or condition;

"(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug in the case described in paragraph (1);

"(3) the Secretary determines that provision of the investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

"(4) the sponsor, or clinical investigator, of the investigational drug submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) and any regulations promulgated under section 505(i) describing the use of investigational drugs in a single patient or a small group of patients.

"(c) TREATMENT INDS.—Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug for eligible patients, the Secretary shall permit such investigational drug to be made available for expanded access under a treatment investigational new drug application if the Secretary determines that—

"(1) under the treatment investigational new drug application, the investigational drug is intended for use in the diagnosis or treatment of a serious or immediately life-threatening disease or condition;

"(2) there is no comparable or satisfactory alternative therapy available to diagnose or treat that stage of disease or condition in the population of patients to which the investigational drug is intended to be administered;

"(3)(A) the investigational drug is under investigation in a controlled clinical trial for the use described in paragraph (1) under an effective investigational new drug application; or

"(B) all clinical trials necessary for approval of that use of the investigational drug have been completed;

"(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug for the use described in paragraph (1) with due diligence;

"(5) the provision of the investigational drug will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i);

"(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

"(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the

product may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) and regulations promulgated under section 505(i). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be of the same type of information that is required by section 402(j)(3) of the Public Health Service Act.

''(d) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug if the requirements under this section are no longer met.''.

SEC. 105. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following:

"(j)(1) The Secretary, acting through the Director of the National Institutes of Health, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

"(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.

"(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store, and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems,

which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

"(3) The data bank shall include the following:

"(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the data bank by the sponsor of the trial not later than 21 days after trials to test clinical effectiveness have begun.

"(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

"(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration under section 551(c) of the Federal Food, Drug, and Cosmetic Act; or

"(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

"(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

"(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal

Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.".

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in section 402(j) of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in section 402(j) of the Public Health Service Act;

(B) on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigation is required to be publicly disclosed; and

(C) on such other issues relating to such section 402(j) as the Secretary may deem appropriate.

SEC. 106. DISSEMINATION OF INFORMATION ON NEW USES.

(a) IN GENERAL.—Chapter VII (2 U.S.C. 371 et seq.), as amended by section 103, is amended by adding at the end the following:

"SUBCHAPTER E—DISSEMINATION OF TREATMENT INFORMATION

"SEC. 745. REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS.

"(a) IN GENERAL.—Notwithstanding sections 301(d), 502(f), and 505 and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate to—

"(1) a health care practitioner,

"(2) a pharmacy benefit manager,

"(3) a health insurance issuer,

"(4) a group health plan, or

"(5) a Federal or State governmental agency,

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug if the manufacturer meets the requirements of subsection (b).

"(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information about a new use of a drug under subsection (a) only if—

"(1) there is in effect for such drug an application filed under section 505(b) or a biologics license issued under section 351 of the Public Health Service Act;

"(2) the information meets the requirements of section 746;

"(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

"(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

"(A) a copy of the information to be disseminated; and

"(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

"(5) the manufacturer has complied with the requirements of section 748 (relating to certification that the manufacturer will submit a supplemental application with respect to such use);

"(6) the manufacturer includes along with the information to be disseminated under this subsection—

"(A) a prominently displayed statement that discloses—

"(i) that the information concerns a use of a drug that has not been approved by the Food and Drug Administration;

"(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

"(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

"(iv) the official labeling for the drug and all updates with respect to the labeling;

"(v) if applicable, a statement that there are products or treatments that have

been approved for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

"(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug for which such information is being disseminated; and

"(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug covered by the information disseminated (unless the information already includes such bibliography).

"(c) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

"(1) additional objective and scientifically sound information that pertains to the safety or effectiveness

of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary or, where appropriate, a summary of such information or any other information that the Secretary has authority to make available to the public; and

"(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug.

"SEC. 746. INFORMATION AUTHORIZED TO BE DISSEMINATED.

"(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate the information on the new use of a drug under section 745 only if the information—

"(1) is in the form of an unabridged—

"(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, which was published in a scientific or medical journal (as defined in section 750(6)), which is about a clinical investigation with respect to the drug, and which would be considered to be scientifically sound by such experts; or

"(B) reference publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug that is the subject of such a clinical investigation; and

"(2) is not false or misleading and would not pose a significant risk to the public health.

"(b) REFERENCE PUBLICATION.—A reference publication referred to in subsection (a)(1)(B) is a publication that—

"(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug;

"(2) has not been edited or significantly influenced by a such a manufacturer;

"(3) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;

"(4) does not focus on any particular drug of a manufacturer that disseminates information under section 745 and does not have a primary focus on

new uses of drugs that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

"(5) presents materials that are not false or misleading.

"SEC. 747. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

"(a) IN GENERAL.—A manufacturer may disseminate information under section 745 only if the manufacturer prepares and submits to the Secretary biannually—

"(1) a list containing the titles of the articles and reference publications relating to the new use of drugs that were disseminated by the manufacturer to a person described in section 745(a) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

"(2) a list that identifies the categories of providers (as described in section 745(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

"(b) RECORDS.—A manufacturer that disseminates information under section 745 shall keep records that may be used by the manufacturer when, pursuant to section 749,

such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to such section. Such records, at the Secretary's discretion, may identify the recipient of information provided pursuant to section 745 or the categories of such recipients.

"SEC. 748. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

"(a) IN GENERAL.—A manufacturer may disseminate information under section 745 on a new use only if—

"(1) the manufacturer meets the condition described in subsection (b) or in subsection (c); or

"(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

"(b) SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF COMPLETED STUDIES.—For purposes of subsection (a)(1), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

"(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

"(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of information under section 745.

"(c) SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.—

"(1) IN GENERAL.—For purposes of subsection (a)(1), a manufacturer may disseminate information on a new use if—

"(A) the manufacturer has submitted to the Secretary an application containing—

"(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

"(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial dissemination of information under section 745 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under this paragraph or paragraph (3)); and

"(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

The Secretary may grant a longer period of time for a manufacturer to submit a supplemental application if the Secretary determines that the studies needed to submit such an application cannot be completed and submitted within 36 months.

"(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

"(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1)(A)(ii) for the completion of studies may be extended by the Secretary if the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner. Such extension may not provide more than 24 additional months.

"(d) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

"(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—

"(A) the manufacturer has submitted to the Secretary an application for an exemption from meeting the requirement of subsection (a)(1); and

"(B)(i) the Secretary has approved the application in accordance with paragraph (2); or

"(ii) the application is deemed under paragraph (3)(A) to have been approved (unless such approval is terminated pursuant to paragraph (3)(B)).

"(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption only if the Secretary determines that—

"(A) it would be economically prohibitive with respect to such drug for the manufacturer to incur the costs necessary for the submission of a supplemental application for reasons, as defined by the Secretary, such as the lack of availability under law of any period during which the manufacturer would have exclusive marketing rights with respect to the new use involved or that the population expected to benefit from

approval of the supplemental application is small; or

"(B) it would be unethical to conduct the studies necessary for the supplemental application for a reason such as the new use involved is the standard of medical care for a health condition.

"(3) TIME FOR CONSIDERATION OF APPLICATION; DEEMED APPROVAL.—

"(A) IN GENERAL.—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.

"(B) TERMINATION OF DEEMED APPROVAL.—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 745 on a new use, the Secretary may at any time terminate such approval and under section 749(b)(3) order the manufacturer to cease disseminating the information.

"(e) REQUIREMENTS REGARDING APPLICATIONS.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

"(f) TRANSITION RULE.—For purposes of this section, in any case in which a manufacturer has submitted to the Secretary a supplemental application for which action by the Secretary is pending as of the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the application is deemed to be a supplemental application submitted under subsection (b).

"SEC. 749. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.

"(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

"(1) CORRECTIVE ACTIONS.—With respect to data received by the Secretary after the dissemination of information under section 745 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public

health, which may include ordering that the manufacturer cease the dissemination of the information.

"(2) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information pursuant to section 745, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

"(b) CESSATION OF DISSEMINATION.—

"(1) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 745 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and

has provided an opportunity for a meeting with respect to such intent unless paragraph (2)(B) applies. If the failure of the manufacturer constitutes a minor violation of this subchapter, the Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

"(2) SUPPLEMENTAL APPLICATIONS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 745 if the Secretary determines that—

"(A) in the case of a manufacturer to which section 748(b) applies, the Secretary determines that the supplemental application received under such section does not contain adequate information for approval of the new use with respect to which the application was submitted; or

"(B) in the case of a manufacturer to which section 748(c) applies, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

"(3) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—If under section 748(d)(3) the Secretary terminates a deemed approval of an exemption, the Sec-

retary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

"(c) CORRECTIVE ACTIONS BY MANUFACTURERS.—

"(1) IN GENERAL.—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary may order the manufacturer to take action to correct the information that has been disseminated, except as provided in paragraph (2).

"(2) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

"SEC. 750. DEFINITIONS.

"For purposes of this subchapter:

"(1) The term 'health care practitioner' means a physician, or other individual who is a provider of

health care, who is licensed under the law of a State to prescribe drugs.

"(2) The terms 'health insurance issuer' and 'group health plan' have the meaning given such terms under section 2791 of the Public Health Service Act.

"(3) The term 'manufacturer' means a person who manufactures a drug, or who is licensed by such person to distribute or market the drug.

"(4) The term 'new use', with respect to a drug, means a use that is not included in the approved labeling of the drug.

"(5) The term 'pharmacy benefit manager' means an organization that—

"(A) manages pharmaceutical costs through—

"(i) pharmacy benefit administration, including claims processing adjudication, pharmacy networks, mail service, and data reporting;

"(ii) formulary management and contracting, including evaluating drugs for formulary status, negotiations of contracts with manufacturers, and disbursement of rebates; and

"(iii) utilization management, including communicating and enforcing therapy guidelines and drug use principles to physicians, pharmacists, and patients; and

"(B) serves 2 principal types of customers which are—

"(i) employers, both private- and public-sector, who use either self-funded health benefits through a third party administrator's insurance carrier or use traditional indemnity coverage, using providers from a preferred provider network or in a fee-for-service capacity; and

"(ii) health maintenance organizations.

"(6) The term 'scientific or medical journal' means a scientific or medical publication—

"(A) that is published by an organization—

"(i) that has an editorial board;

"(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject,

or provide comments about proposed articles; and

"(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

"(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

"(C) that is generally recognized to be of national scope and reputation;

"(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

"(E) that is not in the form of a special supplement that has been funded in whole or in part by 1 or more manufacturers.

"SEC. 751. RULES OF CONSTRUCTION.

"(a) UNSOLICITED REQUEST.—Nothing in section 745 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

"(b) DISSEMINATION OF INFORMATION ON DRUGS NOT EVIDENCE OF INTENDED USE.—Notwithstanding sub-

section (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug, in accordance with section 745, shall not be construed by the Secretary as evidence of a new intended use of the drug that is different from the intended use of the drug set forth in the official labeling of the drug. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug.

"(c) PATENT PROTECTION.—Nothing in section 745 shall affect patent rights in any manner.

"(d) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 745 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 750(6)) from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles from such entity.".

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(x) The dissemination of information in violation of section 745.".

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) SUNSET.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

SEC. 107. STUDIES AND REPORTS.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study—

(1) to determine the impact of the amendments made by section 7 on the resources of the Department of Health and Human Services; and

(2) of the scientific issues raised as a result of the amendments made by section 7, including issues relating to—

(A) the effectiveness of such amendments with respect to the provision of useful scientific information to health care practitioners;

(B) the quality of the information being disseminated pursuant to such amendments;

(C) the quality and usefulness of the information provided, in accordance with such

amendments, by the Secretary or by a manufacturer at the request of the Secretary; and

(D) the impact of such amendments on research in the area of new uses of drugs, indications for new uses, or dosages of drugs for new uses, particularly the impact on pediatric indications and rare diseases.

(b) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study under subsection (a).

SEC. 108. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue final guidances to clarify the requirements for, and

facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary shall designate an individual in each center within the Food and Drug Administration which is responsible for the review of applications for approval of drugs for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and

other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 109. HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care eco-

nomic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.".

SEC. 110. CLINICAL INVESTIGATIONS.

(a) CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: "If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.".

(b) WOMEN AND MINORITIES.—Section 505(b)(1) (21 U.S.C. 355(b)(1)) is amended by adding at the end the following: "The Secretary shall, in consultation with the Director of the National Institutes of Health, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).".

SEC. 111. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 106, is amended by adding at the end the following subchapter:

"SUBCHAPTER F—MANUFACTURING CHANGES

"SEC. 755. MANUFACTURING CHANGES.

"(a) IN GENERAL.—With respect to a drug for which there is in effect an approved application under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

"(1) the holder of the approved application or license (referred to in this section as a 'holder') has validated the effects of the change in accordance with subsection (b); and

"(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

"(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

"(b) VALIDATION OF EFFECTS OF CHANGES.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or

otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety, bioequivalence, bioavailability, or effectiveness of the drug.

"(c) MAJOR MANUFACTURING CHANGES.—

"(1) REQUIREMENT OF SUPPLEMENTAL APPLICATION.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

"(2) CHANGES QUALIFYING AS MAJOR CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that—

"(A) is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the

drug as they may relate to the safety, bioequivalence, bioavailability, or effectiveness of a drug; and

"(B)(i) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary from the requirements of this subsection);

"(ii) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

"(iii) is determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

"(d) OTHER MANUFACTURING CHANGES.—

"(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

"(A) The Secretary may authorize holders to distribute such drugs without prior approval by the Secretary.

"(B) The Secretary may require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

"(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

"(2) CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.—

"(A) SUBMISSION OF REPORT.—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

"(B) AUTHORITY REGARDING ANNUAL REPORTS.—In the case of a holder that during a

single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

"(3) CHANGES REQUIRING SUPPLEMENTAL APPLICATION.—

"(A) SUBMISSION OF SUPPLEMENTAL APPLICATION.—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

"(B) AUTHORITY FOR DISTRIBUTION.—In the case of a manufacturing change to which paragraph (1)(B) applies:

"(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph,

unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

"(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

"(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.".

(b) TRANSITION RULE.—The amendment made by subsection (a) takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act, whichever occurs first.

SEC. 112. STREAMLINING CLINICAL RESEARCH ON DRUGS.

Section 505(i) (21 U.S.C. 355(i)) is amended by adding "(1)" before "The Secretary", by redesignating para-

graphs (1), (2), and (3) as subparagraphs (A), (B), and (C), respectively, by striking the last two sentences, and by adding the following new paragraphs:

"(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including —

"(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

"(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

"(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

"(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

"(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subject of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

"(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will

obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

"(C) Any request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.".

SEC. 113. DATA REQUIREMENTS FOR DRUGS.

Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes, for certain types of studies, when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262). Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 114. CONTENT AND REVIEW OF APPLICATIONS.

(a) SECTION 505(b).—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end the following:

"(4)(A) The Secretary shall issue guidance for the review of applications submitted under paragraph (1) relating to promptness, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards which shall apply equally to all individuals who review such applications.

"(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval under this section or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable request for a meeting, for the purpose of reaching agreement on the design and size of clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

"(C) Agreement regarding the parameters of the design and size of clinical trials of a new drug that are reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the division in which the drug is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

"(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director documents the scientific issue involved.

"(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified. For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug (including all scientific and medical matters, chemistry, manufacturing, and controls).

"(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division de-

termines that a delay is necessary to assure the marketing of a safe and effective drug.".

(b) SECTION 505(j).—

(1) AMENDMENT.—Section 505(j) (21 U.S.C 355(j)) is amended by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively, and by adding after paragraph (2) the following:

"(3)(A) The Secretary shall issue guidance for the review of applications submitted under paragraph (1) relating to promptness, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards which shall apply equally to all individuals who review such applications.

"(B) The Secretary shall meet with an applicant for approval of a drug under this subsection if the applicant makes a reasonable request for a meeting for the purpose of reaching agreement on the design and size of studies needed for approval of such application. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

"(C) Agreements regarding the parameters of design and size of bioavailability and bioequivalence trials of a drug under this subsection that are reached between the Secretary and a sponsor or applicant shall be reduced to writ-

ing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the division in which the drug is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

"(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director documents the scientific issue involved.

"(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified. For purposes of this paragraph, the reviewing division is the division responsible for the review of an application

under this subsection (including scientific matters, chemistry, manufacturing, and controls).

"(F) No action by the reviewing division may at any time be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.".

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is amended—

(A) in paragraph (2)(A)(i), by striking "(6)" and inserting "(7)";

(B) in paragraph (4), by striking "(4)" and inserting "(5)";

(C) in paragraph (4)(I), by striking "(5)" and inserting "(6)"; and

(D) in paragraph (7)(C), by striking "(5)" each place it occurs and inserting "(6)".

SEC. 115. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

"(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public

Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this subsection, or both.

"(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

"(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

"(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

"(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

"(C) a representative of consumer interests and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

"(D) 2 or more members who are specialists or have other expertise in the particular disease or con-

dition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

"(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

"(5) The Secretary shall provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the

Secretary, and the administrative processes and procedures related to panel meetings.

"(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

"(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meeting.

"(8) Within 60 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommenda-

tions of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

"(9) A scientific advisory panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.".

SEC. 116. DISPUTE RESOLUTION.

Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is amended by inserting after section 505A the following:

"DISPUTE RESOLUTION

"SEC. 506. If, regarding an obligation under this Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of this Act or regulation promulgated under this Act provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy by an appropriate scientific advisory panel under section 505(n). Such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 180 days of the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997.".

SEC. 117. INFORMAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

"(h)(1)(A) The Secretary shall develop guidance documents with public participation and ensure that the existence of such documents and the documents themselves are made available to the public both in written form and through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

"(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence.

"(C) For guidance documents that set forth initial interpretations of statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of any guidance documents, unless the Secretary determines that for reasons of the public health need, such prior public participation is not feasible. In such cases, the Secretary shall provide for public comment upon implementation, and take such comment into account.

"(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

"(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents.

"(3) The Secretary, through the Food and Drug Administration, shall maintain electronically and publish periodically in the Federal Register a list of guidance documents. Such list shall be updated quarterly. All such documents shall be made available to the public.

"(4) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate no later than July 1, 2000, on the implementation of these practices.".

SEC. 118. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—

(1) DEFINITION.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(ii) The term 'compounded positron emission tomography drug'—

"(1) means a drug that—

"(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

"(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

"(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.".

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking "; or (3)" and inserting the following: "; or (C) if it is a compounded positron emission tomography drug and the methods

used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)".

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of compounded positron emission tomography drugs and the special techniques and processes required to produce

these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of compounded positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use compounded positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date on which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a compounded positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule, to the extent the notices and rule relate to compounded positron emission tomography drugs:

(1) A notice entitled "Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop", published in the Federal Register on February 27, 1995.

(2) A notice entitled "Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability", published in the Federal Register on April 22, 1997.

(3) A final rule entitled "Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography", published in the Federal Register on April 22, 1997.

(e) DEFINITION.—As used in this section, the term "compounded positron emission tomography drug" has the

meaning given the term in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

SEC. 119. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the

radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, one or more disease states.

(b) DEFINITION.—In this section, the term "radiopharmaceutical" means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 120. MODERNIZATION OF REGULATION.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

"(a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

"(A) a biologics license is in effect for the biological product; and

"(B) each package of the biological product is plainly marked with—

"(i) the proper name of the biological product contained in the package;

"(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

"(iii) the expiration date of the biological product.

"(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

"(B) The Secretary shall approve a biologics license application—

"(i) on the basis of a demonstration that—

"(I) the biological product that is the subject of the application is safe, pure, and potent; and

"(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

"(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).".

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking "(d)(1)" and all that follows through "of this section.";

(B) in paragraph (2)—

(i) by striking "(2)(A) Upon" and inserting "(d)(1) Upon" and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking "subparagraph (A)" and inserting "paragraph (1)"; and

(ii) by striking "this subparagraph" each place it appears and inserting "this paragraph".

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

"(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.".

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking "virus, serum," and all that follows and inserting "biological product.".

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.".

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking "section 351(a)" and inserting "section 351(i)"; and

(B) by striking "262(a)" and inserting "262(i)"; and

(2) in subparagraph (B)(iii), by striking "product or establishment license under subsection (a) or (d)" and inserting "biologics license application under subsection (a)".

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applica-

tions under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

(g) EXAMINATIONS AND PROCEDURES.—Paragraph (3) of section 353(d) of the Public Health Service Act (42 U.S.C. 263a(d)) is amended to read as follows:

"(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures which have been approved by the Food and Drug Administration for home use or which, as determined by the Secretary, are simple laboratory examinations and procedures which have an insignificant risk of an erroneous result, including those which—

"(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

"(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.".

SEC. 121. PILOT AND SMALL SCALE MANUFACTURE.

(a) HUMAN DRUGS.—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end thereof the following:

"(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effective-

ness of the drug and to obtain approval prior to scaling up to a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.".

(b) ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

"(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval prior to scaling up to a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.".

SEC. 122. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—

(1) AMENDMENT.—Section 506 (21 U.S.C. 356), as in effect before the date of the enactment of this Act, is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 301(j) (21 U.S.C. 331(j)) is amended by striking "506, 507,".

(B) Subsection (k) of section 502 (21 U.S.C. 352) is repealed.

(C) Sections 301(i)(1), 510(j)(1)(A), and 510(j)(1)(D) (21 U.S.C. 331(i)(1), 360(j)(1)(A),

360(j)(1)(D)) are each amended by striking ", 506, 507,".

(D) Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by inserting after "503(b)" the following: "or composed wholly or partly of insulin".

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting "or" at the end of subparagraph (B), by striking "; or" at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

(b) CERTIFICATION OF ANTIBIOTICS.—

(1) AMENDMENT.—Section 507 (21 U.S.C. 357) is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out "or 507", section 201(dd) (21 U.S.C. 321(dd)) is amended by striking "507,", and section 201(ff)(3)(A) (21 U.S.C. 321(ff)(3)(A)) is amended by striking ", certified as an antibiotic under section 507,".

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking "507(d) or (g),".

(C) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking "or 507".

(D) Section 502 (21 U.S.C. 352) is amended by striking subsection (l).

(E) Section 520(l) (21 U.S.C. 360j(l)) is amended by striking paragraph (4) and by striking "or Antibiotic Drugs" in the subsection heading.

(F) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting "or" at the end of paragraph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(G) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking ", certification of such drug for such disease or condition under section 507,".

(H) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking "the submission of an application for certification of the drug under section 507,", by inserting "or" at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(I) Section 526(b) (21 U.S.C. 360bb(b)) is amended—

(i) in paragraph (1), by striking ", a certificate was issued for the drug under section 507,"; and

(ii) in paragraph (2) by striking ", a certificate has not been issued for the drug under section 507," and by striking ", approval of an application for certification under section 507,".

(J) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting "or" at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking ", issue another certificate under section 507,".

(K) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking ", if a certification is issued under section 507 for such a drug, or", "of the issuance of the certification under section 507,", and "issue another certification under section 507, or".

(L) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking ", section 507 (d) or (g)".

(M) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting "or" at the end of subparagraph (B), by striking subparagraph (C),

and by redesignating subparagraph (D) as subparagraph (C).

(N) Subparagraphs (A)(ii) and (B) of sections 5(b)(1) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking "or 507".

(O) Section 45C(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking "or 507".

(P) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking "507," each place it occurs.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended by adding at the end thereof the following:

"(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).".

(d) EFFECT.—The amendments made by subsection (b) shall not apply with respect to any application for a drug that contains an active ingredient (including any ester or salt of the active ingredient) that was an antibiotic drug within the meaning of section 507 of such Act and was the subject of an approved or pending application under such

section 507 for certification or exemption from certification before the date of the enactment of this Act.

SEC. 123. FDA MISSION AND ANNUAL REPORT.

(a) MISSION.—Section 903 (21 U.S.C. 393) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

"(b) MISSION.—The Food and Drug Administration shall promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, and with respect to such products shall protect the public health by ensuring that—

"(1) foods are safe, wholesome, sanitary, and properly labeled;

"(2) human and veterinary drugs are safe and effective;

"(3) there is reasonable assurance of safety and effectiveness of devices intended for human use;

"(4) cosmetics are safe and properly labeled; and

"(5) public health and safety are protected from electronic product radiation.

The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, har-

monize regulatory requirements, and achieve appropriate reciprocal arrangements.".

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is amended by adding at the end the following:

"(e) ANNUAL REPORT.—The Secretary shall, simultaneously with the submission each year of the budget for the Food and Drug Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall—

"(1) review the performance of the Food and Drug Administration in meeting its mission and the development of Food and Drug Administration policies to implement such mission;

"(2) review the performance of the Food and Drug Administration in meeting its own performance standards, including its own outcome measurements, and statutory deadlines for the approval of products or for other purposes contained in this Act;

"(3) describe the staffing and resources of the Food and Drug Administration;

"(4)(A) list each bilateral and multinational meeting held by the Food and Drug Administration to address methods and approaches to reduce the bur-

den of regulation, to harmonize regulation, and to seek appropriate reciprocal arrangements, (B) describe the goals, activities, and accomplishments of the Food and Drug Administration in such meetings, and (C) list issues that the Food and Drug Administration is considering or has presented for each such meeting.''.

SEC. 124. INFORMATION SYSTEM.

Chapter IX is amended by adding at the end the following section:

''SEC. 906. INFORMATION SYSTEM.

''The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.''.

SEC. 125. EDUCATION AND TRAINING.

Chapter IX, as amended by section 124, is amended by adding at the end the following sections:

''SEC. 907. EDUCATION.

''The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for sci-

entific training and training in administrative process and procedure and integrity issues.".

SEC. 126. CENTERS FOR EDUCATION AND RESEARCH ON DRUGS.

Chapter IX, as amended by section 125, is amended by adding at the end the following section:

"SEC. 908. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON DRUGS.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

"(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:

"(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

"(A) To increase awareness of new uses of drugs and the unforeseen risks of new uses of drugs.

"(B) To provide objective clinical information to the following entities:

"(i) Health care practitioners or other providers of health care goods or services.

"(ii) Pharmacy benefit managers.

"(iii) Health maintenance organizations or other managed health care organizations.

"(iv) Health care insurers or governmental agencies.

"(C) To improve the quality of health care while reducing the cost of health care through the prevention of adverse effects of drugs and the consequences of such effects, such as unnecessary hospitalizations.

"(2) The conduct of research on the comparative effectiveness and safety of drugs.

"(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

"(c) APPLICATION FOR GRANT.—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(d) PEER REVIEW.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1998, and $3,000,000 for fiscal year 1999.".

SEC. 127. HARMONIZATION.

Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

"(c) The Secretary shall participate in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act. The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under subsection (b).".

SEC. 128. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII, as amended by section 111, is amended by adding at the end the following:

''SUBCHAPTER G—ENVIRONMENTAL IMPACT REVIEW

''SEC. 761. ENVIRONMENTAL IMPACT REVIEW.

''Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published at part 25 of 21 C.F.R. (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act.''.

SEC. 129. NATIONAL UNIFORMITY.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 128, is amended by adding at the end the following:

''SUBCHAPTER H—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS FOR HUMAN USE AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

''SEC. 771. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS FOR HUMAN USE.

''(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

"(1) that relates to the regulation of a drug intended for human use that is not subject to the requirements of section 503(b)(1); and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

"(1) protects an important public interest that would otherwise be unprotected;

"(2) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

"(3) would not unduly burden interstate commerce.

"(c) SCOPE.—

"(1) IN GENERAL.—This section shall not apply to—

"(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

"(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

"(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

"(d) EXCEPTIONS.—

"(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or 507 or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

"(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

"(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of this section.

"(2) STATE INITIATIVES.—This section shall not apply to a State public initiative enacted prior to the date of enactment of this section.

"(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.".

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking "prescription drugs" each place it appears and inserting "prescription drugs, nonprescription drugs intended for human use,".

(c) MISBRANDING.—Paragraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

"(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

"(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

"(ii) the established name and quantity or, if deemed appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if deemed appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

"(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if deemed appro-

priate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, but nothing in this clause shall be deemed to require that any trade secret be divulged, except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and this subclause shall not apply to nonprescription drugs not intended for human use.

"(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of clause (A)(ii) or (iii) or this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(d) COSMETICS.—Subchapter H of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

"SEC. 772. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

"(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), a State or political subdivision of a State shall not impose or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with a requirement that is specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling and packaging that—

"(1) protects an important public interest that would otherwise be unprotected;

"(2) would not cause a cosmetic to be in violation of any applicable requirements or prohibition under Federal law; and

"(3) would not unduly burden interstate commerce.

"(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

"(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.".

SEC. 130. FDA STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

(a) LIST AND ANALYSIS.—The Secretary of Health and Human Services shall, through the Food and Drug Administration—

(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds, and

(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of the enactment of this section and shall provide the analysis required by paragraph (2) within 2 years of such date of enactment.

(b) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made of such use.

(c) STUDY OF MERCURY SALES.—

(1) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration and subject to appropriations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on humans of the use of elemental, organic or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

(A) the scope of mercury use as a drug or dietary supplement; and

(B) the adverse effects on health of children and other sensitive populations resulting from

exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent the Secretary believes necessary or appropriate, with any other Federal or private entity.

(2) REGULATIONS.—If, in the opinion of the Secretary, the use of elemental, organic or inorganic mercury offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 129, is further amended by adding at the end the following:

"Subchapter I—Notification of the Discontinuance of a Life Saving Product

"SEC. 781. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

"(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug (including a biological product) or device—

"(1) that is—

"(A) life supporting;

"(B) life sustaining; or

"(C) intended for use in the prevention of a debilitating disease or condition; and

"(2) for which an application has been approved under section 505(b), 505(j), or 515(d),

shall notify the Secretary of a discontinuance of the manufacture of the drug or device at least 6 months prior to the date of the discontinuance.

"(b) REDUCTION IN NOTIFICATION PERIOD.—On application of a manufacturer, the Secretary may reduce the notification period required under subsection (a) for the manufacturer if good cause exists for the reduction, such as a situation in which—

"(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

"(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

"(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

"(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer; or

"(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code.

"(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs and devices described in subsection (a) to appropriate physician and patient organizations.".

TITLE II—IMPROVING REGULATION OF DEVICES

SEC. 201. DISPUTE RESOLUTION.

Section 506, as added by section 116, is amended in the first sentence by inserting before the period the following: ", or under section 515(g)(2)(B), as applicable".

SEC. 202. INVESTIGATIONAL DEVICE EXEMPTIONS; EXPANDED ACCESS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

"(6)(A) Not later than 120 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, the following:

"(i) Procedures and conditions under which the Secretary will, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

"(I) developmental changes in the device that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

"(II) changes or modifications to clinical protocols that do not affect the validity of data or information resulting from the completion of an approved protocol and do not alter the relationship of likely patient risk to benefit relied upon to approve a protocol.

"(ii) Procedures and conditions under which the Secretary will, outside of an approved investigational protocol (subject to compliance with regulations for the protection of patients), permit uses of the device in the diagnosis, monitoring, or treatment of diseases or conditions that are life-threatening or could be irreversibly debilitating, when—

"(I) the treating physician determines that the investigational use of the device likely will provide a benefit; that the risk of not using the device exceeds the probable risk of using the device; and that there is no legally marketed device alternative for the satisfactory treatment or diagnosis of such disease or condition;

"(II) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the investigational use of the device in the case described in subclause (I);

"(III) the Secretary determines that the investigational use of the device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

"(IV) the sponsor, or clinical investigator, of the investigational use of the device submits to

the Secretary a clinical protocol consistent with the provisions of paragraph (3) and any regulations promulgated under such paragraph describing the investigational use of devices in a single patient or a small group of patients.

"(B) Regulations under subparagraph (A)(i) shall provide that a change or modification described in such subparagraph is not permitted unless, not later than 5 days after making the change or modification, a notice of the change or modification is submitted to the Secretary.

"(C) Regulations under subparagraph (A)(ii) shall provide that, under appropriate conditions described by the Secretary in the regulations, the Secretary will authorize the shipment of investigational devices (as defined in the regulations) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

"(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review board, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant requests a meeting with the Secretary regarding such review, the Sec-

retary shall meet with the applicant not later than 30 days after receiving the request for the meeting.

"(B) Agreements regarding the parameters of an investigational plan (including clinical protocol) that are reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreements shall not be changed, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

"(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.".

SEC. 203. SPECIAL REVIEW FOR CERTAIN DEVICES.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) by adding at the end the following:

"(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

"(A) representing breakthrough technologies,

"(B) for which no approved alternatives exist,

"(C) which offer significant advantages over existing approved alternatives, or

"(D) the availability of which is in the best interest of the patients.".

SEC. 204. EXPANDING HUMANITARIAN USE OF DEVICES.

(a) SECTION 520(m).—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by inserting after and below subparagraph (C) the following:

"The request shall be in the form of an application to the Secretary. Within 60 days of the date of the receipt of an application, the Secretary shall issue an order approving or denying the application, except that if the Secretary convenes a scientific advisory panel, the Secretary shall within 120 days of the receipt of an application issue such order.";

(2) by amending paragraph (5) to read as follows:

"(5) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device, after providing notice and an opportunity for an informal hearing, if any condition for granting such exemption for such device set forth in paragraphs (2) through (4) no longer is met."; and

(3) by amending paragraph (6) to read as follows:

"(6) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.".

(b) REGULATIONS.—Any provision in a regulation included in title 21 of the Code of Federal Regulations pertaining to humanitarian devices which is inconsistent with the amendments made by subsection (a) shall be deemed rescinded on the date of the enactment of this Act. The Secretary shall amend regulations pertaining to humanitarian devices to conform with the amendments made by subsection (a).

SEC. 205. DEVICE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end thereof the following:

"(c) LISTING OF RECOGNIZED STANDARDS.—(1) The Secretary shall issue notices identifying and adopting applicable nationally or internationally recognized standards (or portions of such standards) to which a person may self-certify compliance for the purpose of demonstrating a reasonable assurance that a device is safe or effective or to determine compliance with any requirement of this Act. Such notices shall be published in the Federal Register, and the Secretary shall provide an opportunity for public comment on the standards involved.

"(2) The Secretary shall accept a certification that a device conforms with each type of standard referenced in subsection (a) and identified in such certification to the extent such standard applies, except that the Secretary may, at any time, require the person who submitted the certification to submit the data and information which such person relied upon in making such certification, and may reject the certification if the Secretary determines that the data and information do not demonstrate compliance with the standards identified in the certification. Such person shall maintain the data and information for a period of

2 years after the submission of the certification, or for the expected design life of the device, whichever is later.

"(3) The Secretary may remove from the list of standards adopted under subsection (a) a standard (or portion of a standard) which the Secretary determines is not reliable for the purpose set out in such subsection.

"(4) In the case of a person who does not self-certify compliance pursuant to paragraph (1) regarding a device, the person may elect to utilize data other than those required by standards under paragraph (1) to demonstrate a reasonable assurance of the safety or effectiveness of the device.".

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 106(b), is amended by adding at the end the following:

"(y) The falsification of a certification under section 514(c) or the failure or refusal to provide data or information required by the Secretary under such section.".

(c) ADULTERATED DEVICES.—Section 501(e) (21 U.S.C. 351(e)) is amended by striking "subject to a performance standard" and all that follows and inserting the following: "subject to a performance standard established under subsection (b) of section 514, unless such device is in all respects in conformity with such standard; or subject to a standard listed under subsection (c) of such section (in

the case of a person who has self-certified to such standard), unless such device is in all respects in conformity with such standard.".

(d) CONFORMING AMENDMENTS.—

(1) DEFINITION OF CLASS II DEVICE.—Section 513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B) is amended by inserting after "performance standards," the following: "the listing of standards under section 514(c),".

(2) RELATIONSHIP TO PERFORMANCE STANDARDS.—Section 514(a) (21 U.S.C. 360d(a)) is amended—

(A) in paragraph (1), in the second sentence, by striking "under this section" and inserting "under subsection (b)";

(B) in paragraph (2), in the matter preceding subparagraph (A), by striking "under this section" and inserting "under subsection (b)";

(C) in paragraph (3), by striking "under this section" and inserting "under subsection (b)"; and

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking "this section" and inserting "this subsection and subsection (b)".

SEC. 206. SCOPE OF REVIEW.

(a) SECTION 513(a).—Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended—

(1) in subparagraph (A) by inserting "one or more" before "clinical investigation"; and

(2) by adding at the end the following:

"(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

"(D)(i) Upon the request of any person intending to submit an application under section 515, the Secretary shall, not later than 30 days after receiving such request, meet with the person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the proposed conditions of use. Within 30 days of such meeting, the Secretary shall identify, and confirm in writing, the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the proposed conditions of use.

"(ii) Agreements under section 515 regarding the parameters of valid scientific evidence for a device that are

reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreements shall not be changed, except—

"(I) with the written agreement of the sponsor or applicant; or

"(II) pursuant to a decision, made in accordance with clause (iii) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device has been identified.

"(iii) A decision under clause (ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.".

(b) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

"(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

"(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

"(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k), unless the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the 'Director'), after providing an opportunity for consultation with the person who submitted such report, determines and states in writing (I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device, and (II) on the basis of data or the absence of data, that such use could cause harm.

"(ii) Such determination shall—

"(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

"(II) specify limitations on the device's labeling which proscribe the use not included in proposed labeling; and

"(III) find the device substantially equivalent when the labeled intended use and the technological characteristics of the device relative to a legally marketed device conform with the requirements of subparagraph (A).

"(iii) The responsibilities of the Director under this subparagraph may not be delegated.

"(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997.".

(c) SECTION 515(d).—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by adding after and below clause (ii) the following:

"In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly

evaluate all material facts pertinent to the proposed labeling.''; and

(2) by adding after paragraph (5) (as added by section 5(2)) the following:

''(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

''(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to

review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

"(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

"(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

"(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

"(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.".

SEC. 207. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k)—

(A) in the matter preceding paragraph (1), by adding after "report to the Secretary" the fol-

lowing: "or person who is accredited under section 712(a)"; and

(B) by adding after and below paragraph (2) the following:

"Such a report is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (l) or is classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended to be life supporting or life sustaining or is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury. With respect to a person who is accredited under section 712(a), such accredited person shall review a report under this subsection that is received by such person and shall submit, not later than 60 days after receiving the report, to the Secretary such person's recommendation for action to be taken by the Secretary on the report."; and

(2) by adding after subsection (k) the following subsection:

"(l) Not later than 30 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device

that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device listed by the Secretary shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that is 1 day after the date of the publication of the list, any person may petition the Secretary to exempt a type of class II device from the reporting requirement of subsection (k). The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. If the Secretary fails to respond to a petition within 120 days of receiving it, the petition shall be deemed to be granted.''.

(b) INITIAL CLASSIFICATION.—Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in the second sentence of paragraph (1) by striking the period at the end and inserting the following: ''unless within 30 days of receiving an order classifying the device into class III the person who submits a report under section 510(k) for such device requests review with respect to the classification of the device and a final order of classification from the Secretary. Such person shall submit to the Secretary data and information supporting the classification of

the device into class I or II. After the request, a device classified into class III under this paragraph remains in class III, but shall not be deemed to be finally classified until the Secretary has determined the classification of the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), within 60 days of receiving the request to review and classify a device. Any device found under this paragraph not to be substantially equivalent to a device described in subparagraph (A)(i) and which is classified by the Secretary into class III may not be commercially distributed in commerce before it is approved under section 515.''; and

(2) by adding at the end the following:

''(4) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that the failure to comply with such regulations is directly related to the safety or effectiveness of the device).''.

(c) SECTION 513.—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 206(b), is amended—

(1) in subparagraph (A)(ii)(I), by striking "clinical data" and inserting "appropriate clinical or scientific data" and by inserting "or a person accredited under section 712" after "Secretary";

(2) in subparagraph (A)(ii)(II), by striking "efficacy" and inserting "effectiveness"; and

(3) by adding at the end of paragraph (1) the following:

"(F) For purposes of subparagraph (A), the term 'legally marketed device' includes any device introduced into interstate commerce for commercial distribution before May 28, 1976, and any device determined to be substantially equivalent to such device which has not been removed from the market by an order of the Secretary or a judicial order because it is not safe or not effective.

"(G) Not later than 270 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).".

(d) SUNSET.—The amendments made by subsections (a)(1)(A) and (c)(1), to the extent that they relate to an accredited person under section 712 of the Federal Food, Drug, and Cosmetic Act, shall be of no force or effect upon the expiration of 7 years from the date of the enactment of this Act.

SEC. 208. CLASSIFICATION PANELS.

Section 513(b) (21 U.S.C. 360c(b)) is amended by adding at the end the following:

"(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

"(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have the same rights as the Secretary regarding—

"(i) access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code);

"(ii) the submission, for review by a classification panel, of information that is based on the data or information provided in the application submitted under section 515 by the person, which information

shall be submitted to the Secretary for prompt transmittal to the classification panel; and

"(iii) the participation of the persons at meetings of the panel.

"(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

"(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

"(8) A scientific advisory panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.".

SEC. 209. PREMARKET APPROVAL.

Section 515(d) (21 U.S.C. 360e(d)), as amended by section 203(1), is amended by inserting after paragraph (1) the following:

"(2) Each application received under subsection (c) shall be reviewed in a manner to achieve final action on such application within 180 days of its receipt. At the request of the applicant, the Secretary shall meet with an applicant under such an application within 90 days of the date of the application's submission.".

SEC. 210. ACCREDITATION FOR ACCREDITED PERSONS.

(a) AMENDMENT.—Subchapter A of chapter VII is amended by adding at the end the following:

"ACCREDITED PERSONS

"SEC. 712. (a) IN GENERAL.—The Secretary shall, not later than 1 year after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, accredit persons for the purpose of reviewing and initially classifying devices under section 513(f)(1) that are subject to a report under section 510(k). An accredited person may not be used to perform a review of a class III device, or a class II device which is intended to be permanently implantable or life sustaining or life supporting.

"(b) ACCREDITATION.—

"(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered

by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

"(2) ACCREDITATION.—

"(A) GENERAL RULE.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register requirements to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

"(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person acts in a manner that is inconsistent with the purposes of this section or poses a threat to public health or

fails to act in a manner that is consistent with the purposes of this section.

"(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

"(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

"(ii) take such additional measures as the Secretary determines to be appropriate.

"(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(e)(2) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

"(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

"(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices

and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

"(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

"(C) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

"(D) Such person shall be operated in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

"(i) certify that reported information accurately reflects data reviewed;

"(ii) limit work to that for which competence and capacity are available;

"(iii) treat information received, records, reports, and recommendations as proprietary information;

"(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

"(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person

who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

"(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least 2 or more accredited persons from which the regulated person may select 1 for a specific regulatory function.".

(b) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 205(b), is amended by adding at the end the following:

"(z) In the case of a drug, device, or food—

"(1) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

"(2) the disclosure by a person accredited under section 712 of confidential commercial information or any trade secret without the express written consent

of the person who submitted such information or secret to such person; or

"(3) the receipt by a person accredited under section 712 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.".

(c) SUNSET.—The amendments made by subsections (a) and (b) to the extent they relate to an accredited person under section 712 of the Federal Food, Drug, and Cosmetic Act shall be of no force or effect upon the expiration of 7 years from the date of the enactment of this Act.

(d) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on the use of accredited persons under section 712 of the Federal Food, Drug, and Cosmetic Act, the extent to which such use was helpful in the implementation of such Act, and the extent to which such use promoted actions which were contrary to the purposes of such Act.

SEC. 211. PREAMENDMENT DEVICES.

Section 515(i) (21 U.S.C. 360e(i)) is amended to read as follows:

"Revision

"(i) Not later than 180 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of the types of devices classified into class III under section 513(d), which are not subject to a regulation under subsection (b), and for which the Secretary has determined after classification of such devices that premarket approval is unnecessary to protect the public health. Each such type of device listed in the Federal Register publication shall be reclassified into class II or class I, as appropriate.".

SEC. 212. DEVICE TRACKING.

Subsection (e) of section 519 (21 U.S.C. 360i) is amended to read as follows:

"Device Tracking

"(e) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

"(1) the failure of which would be reasonably likely to have serious adverse health consequences; or

"(2) which is—

"(A) intended to be an implantable device, or

"(B) a life sustaining or life supporting device used outside a device user facility.".

SEC. 213. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360l) is amended to read as follows:

"POSTMARKET SURVEILLANCE

"SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

"(1) an implantable device, or

"(2) a life-sustaining or life-supporting device used outside a device user facility.

"(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if such plan will result in information necessary to determine the occurrence of unforeseen events. The

Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 506A.".

SEC. 214. HARMONIZATION.

(a) SECTION 520(f).—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended by striking "and" at the end of clause (i), by striking the period at the end of clause (ii) and inserting "; and" and by adding after clause (ii) the following:

"(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts thereof, for medical devices.".

(b) SECTION 803.—Section 803 (21 U.S.C. 383), as amended by section 127, is amended in subsection (c)—

(1) by adding at the end the following sentence: "The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, make public a plan that establishes a framework for achiev-

ing mutual recognition of good manufacturing practices inspections.";

(2) by inserting "(1)" after "(c)"; and

(3) by adding at the end the following:

"(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).".

SEC. 215. REPORTS.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "manufacturer, importer, or distributor" and inserting "manufacturer or importer"; and

(B) by striking paragraph (9) and inserting the following:

"(9) shall require distributors to keep records and make such records available to the Secretary upon request.";

(2) by striking subsection (d); and

(3) in subsection (f), by striking ", importer, or distributor" each place it appears and inserting "or importer".

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3) the following:

"(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or"; and

(3) by adding at the end the following flush sentence:

"In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.".

(c) DEVICE USER FACILITIES.—

(1) IN GENERAL.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) in paragraph (1)(C)—

(i) in the first sentence, by striking "a semi-annual basis" and inserting "an annual basis";

(ii) in the second sentence, by striking "and July 1"; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting "or" after the comma at the end;

(ii) in subparagraph (B), by striking ", or" at the end and inserting a period; and

(iii) by striking subparagraph (C).

(2) SENTINEL SYSTEM.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) by redesignating paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraph:

"(5) With respect to device user facilities that are hospitals or nursing homes:

"(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of hospitals and nursing homes that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

"(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply to such device user facilities.

"(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply to such facilities except to the extent that the Secretary determines otherwise.

"(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to such a facility unless the facility is included in the subset referred to in subparagraph (A).

"(E) Not later than one year after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.".

SEC. 216. PRACTICE OF MEDICINE.

Chapter IX, as amended by section 126, is amended by adding at the end the following:

"SEC. 909. PRACTICE OF MEDICINE.

"Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.".

SEC. 217. CLARIFICATION OF DEFINITION.

Section 201(h) (21 U.S.C. 321) is amended by adding at the end the following: "A computer software product shall not be considered a device under this paragraph solely on the basis that the primary use of such product is related to the provision of health care.".

SEC. 218. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

Section 301 (21 U.S.C. 331) is amended by striking paragraph (l).

SEC. 219. FDA ANNUAL REPORT.

Section 903 (21 U.S.C. 393), as amended by section 123(b), is amended in subsection (e)—

(1) by striking the period at the end of paragraph (4) and inserting "; and"; and

(2) by adding at the end the following:

"(5) summarize and explain each instance in the previous fiscal year in which an application received under section 515(c) was not reviewed in a manner to achieve final action on such application within 180 days of its receipt.".

SEC. 220. INFORMATION SYSTEM.

Section 906, as added by section 124, is amended by adding at the end the following: "With respect to devices, the system shall permit access by the applicant under conditions specified by the Secretary.".

SEC. 221. NONINVASIVE BLOOD GLUCOSE METER.

(a) FINDINGS.—The Congress finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetes total nearly $100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(7) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children; and

(9) the Food and Drug Administration is responsible for reviewing all applications for new medical devices in the United States.

(b) SENSE OF CONGRESS.—It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and

well-being of all people with diabetes across America and the world.

SEC. 222. RULE OF CONSTRUCTION.

Nothing in this title or the amendments made by this title shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

TITLE III—IMPROVING REGULATION OF FOOD

SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by adding at the end the following:

"(D) Subject to the time period in the last sentence of clause (A)(i), proposed regulations under this paragraph may be made effective upon publication at the discretion of the Secretary, notwithstanding the provisions of section 553 of title 5, United States Code, pending consideration of public comment and publication of a final regulation. Such regulations shall be deemed final agency action for purposes of judicial review.".

SEC. 302. PETITIONS FOR CLAIMS.

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: "If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.";

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma the following: "or the petition is deemed to be denied"; and

(3) by adding at the end the following: "If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue such a proposed regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the proposed regulation did not occur within such 540 days.".

SEC. 303. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following:

"(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a

notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the

scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(D) A claim submitted under the requirements of clause (C) may be made until—

"(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D)) under the standard in clause (B)(i)—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.".

SEC. 304. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

"(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a

bibliography of such literature, relating to the nutrient level to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(H) A claim submitted under the requirements of clause (G) may be made until—

"(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D))—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.".

SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

"(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the

Secretary shall take into account the significance of the food in the total daily diet.".

SEC. 306. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

"DISCLOSURE

"SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

"(b) In this section, the term 'radiation disclosure statement' means a written statement or symbol that discloses that a food has been intentionally subject to radiation.".

SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall—

(1) make a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act; or

(2) provide the Committee on Commerce of the House of Representatives and the Committee on Labor

and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 308. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based paints in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED PAINT.—Lead and cadmium based paint may not be banned as an unapproved food additive if it is on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim; and

(2) which is not, by design, representation, or custom of usage intended for use by children.

SEC. 309. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subsection (j)"; and

(B) by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive that is a food contact substance, there is—

"(A) in effect for such substance a regulation issued under this section prescribing the conditions under which such substance may be safely used and such substance and the use of such substance are in conformity with such regulation; or

"(B) a notification submitted under subsection (h) that is in effect."; and

(4) in the flush matter following paragraph (3) (as added by paragraph (3)), by inserting "or notification" after "regulation" each place it appears.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

"Notification Relating to a Food Contact Substance

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a person manufacturing or supplying a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the—

"(A) name of the person;

"(B) identity and intended use of the food contact substance; and

"(C) determination of the person that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A).

The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

"(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless, within the 120-day period, the Secretary—

"(i) makes a determination that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to

be safe under the standard described in subsection (c)(3)(A), or

"(ii) makes a determination under paragraph (3) with respect to the need for a petition under subsection (b) for such food contact substance,

and informs the person of such determination.

"(B) A determination by the Secretary under subparagraph (A)(i) shall constitute final agency action subject to judicial review.

"(C) A notification under this subsection shall be effective only with respect to the person identified in the notification.

"(3)(A) The notification process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and the person manufacturing or supplying the food contact substance agree that such person should submit a petition under subsection (b).

"(B) The Secretary may promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b) and shall consider criteria such as the probable consumption of a food contact substance and potential toxicity of the food contact substance in determining

the circumstances in which a petition shall be filed under subsection (b) with respect to the food contact substance.

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.";

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: "The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to be no longer in effect."; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking "subsections (b) to (h)" and inserting "subsections (b) to (i)".

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as

added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 310. MARGARINE.

(a) SECTION 301(m).—Paragraph (m) of section 301 (21 U.S.C. 331) is amended by striking "section 407(b) or 407(c)" and inserting "section 407".

(b) SECTION 407.—Section 407 (21 U.S.C. 347) is amended to read as follows:

"OLEOMARGARINE AND MARGARINE

"SEC. 407. No person shall sell, or offer for sale, oleomargarine or colored margarine unless the principal display panel of such oleomargarine or margarine bears as one of its principal features the word 'oleomargarine' or 'margarine' which is in—

"(1) bold type on such panel;

"(2) a size reasonably related to the most prominent printed matter; and

"(3) lines generally parallel to the base on which the package rests as it is designed to be displayed.".

(c) ACT OF MARCH 16, 1950.—Sections 3(a) and 6 of the Act of March 16, 1950 (21 U.S.C. 347a, 347b) are repealed.

SEC. 311. EFFECTIVE DATE.

The amendments made by this title shall take effect on the date of the enactment of this Act.

Amend the title so as to read ''An Act to amend the Federal Food, Drug, and Cosmetic Act to improve the regulation of food, drugs, cosmetics, and devices, and for other purposes.''.

Attest:

Clerk.